

**REMARKS****BRIEF SUMMARY OF INTERVIEW**

Initially, Applicants express appreciation to Examiner Salvoza and Supervisor Jim Housel for the telephone conference on August 9, 2005 with Applicants' representatives, Arnold Turk and Tu Phan. During the telephone conference, Applicants' representatives addressed the rejections asserted in the Office Action mailed May 3, 2005. In particular, Applicants pointed out that the claimed invention is a method of recovering a budded baculovirus expressing an intracellular organelle unfused membrane-bound protein. Applicants presented arguments that because the organelle membrane-bound protein is recovered from the viral envelope of the budded baculovirus, the protein is not fused to the coat protein of the virus or the cell membrane of the host cell. Applicants also noted that the prior art of record does not teach or suggest the recovery of a budded baculovirus expressing an intracellular organelle membrane-bound protein. In addition, Applicants pointed out that unfused proteins are inherently supported by Applicants' originally filed disclosure, and pointed to pages 1-2, and the Examples at pages 22-24 showing that the genes integrated in the vector encoding the organelle membrane-bound protein are not fused to any other protein.

The Examiner indicated that they would further review the application, and advise regarding possible allowable subject matter and suggested claim amendments.

Applicants also express appreciation for the telephone interview on August 18, 2005, wherein Examiner Salvoza suggested amendments to the claims to place the

application into condition for allowance. The Examiner suggested removing the term "unfused" from the claims and specification because the term is not explicitly expressed in the originally filed application, and including the language "said infected host allowing baculovirus produced in said host to bud and be released from said host with said expressed protein being in the envelope of said budded baculovirus" in claims 1, 2, 21, and 25.

#### **SUMMARY OF STATUS OF AMENDMENTS**

In the present amendment, claims 1-6 and 15-28 will be amended, with claims 1, 2, 21, and 25 being independent claims. Claims 1-8 and 15-28 will remain pending and under consideration. Furthermore, the claims and specification have been amended to remove the term "unfused" and the claims have been amended in the manner suggested by the Examiner in the telephone interviews discussed above to place the application into condition for allowance.

Reconsideration and allowance of the application are respectfully requested.

#### **OBJECTION TO THE SPECIFICATION**

The amendment filed on October 29, 2004, is objected to under 35 U.S.C. § 132(a) because the amendment allegedly introduces new matter into the disclosure. The Office Action asserts that the recitation of "unfused" is not supported by the original disclosure and requires that the recitation be canceled in reply to the Office Action.

In response, Applicants respectfully note that one of skill in the art would understand from reading the specification and examples, that the term “unfused” is inherently disclosed and supported by the original disclosure. However, in order to advance prosecution of the present application, and without acquiescence, Applicants have amended the specification and claims to remove the term “unfused.”

Accordingly, the ground of objection should be withdrawn.

#### **RESPONSE TO 35 U.S.C. §112, FIRST PARAGRAPH REJECTION**

Claims 1-6 and 15-28 are rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. The Office Action asserts that adding the term “unfused” to the specification does not reasonably convey to one skilled in the art the intended meaning or breadth of the term. For example, the Office Action alleges that to one of ordinary skill in the art the word “unfused” could still “mean fused, conjugated, coupled, attached, covalently or non-covalently attached, attached to a molecule, gene, protein or moiety, or fused naturally or fused synthetically.”

In response, Applicants note that “unfused” is inherently disclosed and supported by the originally filed disclosure, and that one of ordinary skill in the art would understand, from reading the specification, especially at pages 1-2 and the Examples at pages 22-24, that the genes integrated in the vector encoding the organelle membrane-bound protein in the claimed method for recovering a budded baculovirus expressing an intracellular organelle membrane-bound protein, is not fused to any other protein. Furthermore, because the organelle membrane-bound protein is recovered in the viral envelope, the

organelle membrane-bound protein is not fused to the coat protein of the virus or the cell membrane of the host cell. However, in order to advance prosecution of the application, the explicit recitation of “unfused” has been removed from the amendments made to the claims.

For these reasons, the rejection to claims 1-6 and 15-28 under 35 U.S.C. § 112, first paragraph should be withdrawn.

## **RESPONSE TO REJECTIONS BASED UPON PRIOR ART**

Claims 1-8 and 15-28 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lanford et al. (J. Virology 1989; 63(4): 1549-1557) (“Lanford”), Possee (Current Opinion in Biotechnology. 1997; 8: 569-572) (“Possee”), Nohturefft et al. (PNAS 1999; 96: 11235-11240) (“Nohturefft”), and Duncan et al. (Journal of Biological Chemistry. 1997; 272(19): 12778-12785) (“Duncan”).

The rejection asserts that Lanford teaches use of baculovirus system to express a gene product in both fusion and nonfusion forms, or “unfused,” polypeptides. In particular, the Office Action points to the alleged construction of nonfusion vectors with the initiation codon altered to prevent the synthesis of a fusion protein in Lanford at page 1555, bottom of second column, and spanning page 1556.

The rejection asserts that one of skill in the art at the time the invention was made would have been motivated to combine Lanford to express any protein of interest in a baculovirus in view of Possee, page 570, second column, first full paragraph. The rejection also asserts that Nohturefft and Duncan teach expression of SREPBs in the ER and Golgi

Apparatus, respectively. The rejection alleges that Lansford points to a reasonable expectation of success, since the level of nonfusion proteins created by nonfusion vectors is allegedly comparable to the level of fusion proteins created by fusion vectors in Lansford at pages 1555-1556.

Applicants note that during the August 18, 2005, telephone interview discussed above, arguments as included in Applicants response filed October 29, 2004, were emphasized and the Examiner indicated that amendments to the claims in the manner suggested by the Examiner would place the application into condition for allowance. For the sake of brevity, Applicants are not repeating these arguments, and are herein incorporating by reference these arguments.

Accordingly, the presently claimed invention is not taught or suggested by any of the prior art cited in the Office Action. For these reasons, Applicants respectfully request that the rejection of claims 1-8 and 15-28 under 35 U.S.C. §103(a) should be withdrawn.

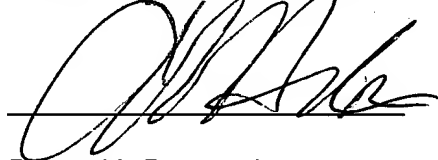
**CONCLUSION**

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the rejection of record, and allow all the pending claims.

Allowance of the application is requested, with an early mailing of the Notices of Allowance and Allowability.

If the Examiner has any questions or wish to further discuss this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,  
Takao HAMAKUBO et al.

A handwritten signature in black ink, appearing to read 'B. Bernstein', is written over a horizontal line.

Bruce H. Bernstein  
Reg. No. 29,027

August 31, 2005  
GREENBLUM & BERNSTEIN, P.L.C.  
1950 Roland Clarke Place  
Reston, VA 20191  
(703) 716-1191

Arnold Turk  
Reg. No. 33,094